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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/773,823

02/06/2004

Bernhard Keppler

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EXAMINER

JONES, DAMERON LEVEST

ART UNIT

PAPER NUMBER

1618

DATE MAILED: 06/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/773,823

Applicant(s)

KEPPLER, BERNHARD

Examiner

D. L. Jones

Art Unit

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 5/18/04 → 2/6/04
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>5/18/04</u> & <u>2/6/04</u> . | 6) <input type="checkbox"/> Other: _____ |

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APPLICANT'S INVENTION

1. Applicant's invention is direct to compounds and uses thereof as set forth in claims 1, 3, and 6.

Note: Claims 1-6 are pending.

112 FIRST PARAGRAPH REJECTIONS

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 6 is rejected under 35 U.S.C. 112, first paragraph, because the specification does not provide enablement for the preventing of cancer diseases. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

There are several guidelines when determining if the specification of an application allows the skilled artisan to practice the invention without undue experimentation. The factors to be considered in determining what constitutes undue experimentation were affirmed by the court in *In re Wands* (8 USPQ2d 1400 (CAFC 1986)). These factors are the quantity of experimentation; the amount of direction or

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guidance presented in the specification; the presence or absence of working examples; the nature of the invention; the state of the prior art; the level of skill of those in the art; predictability or unpredictability of the art; and the breadth of the claims.

The disclosure of the instant invention is directed to compounds of formula I which may be used to treating or preventing cancer as set forth in dependent claim 6. However, the prevention of cancer diseases is inconsistent with what is known in the art since it is known in the art to administer drugs which inhibit cancer, but not prevent cancer. Furthermore, prevention of cancer indicates that the subject never experiences any characteristics associated with cancer. Hence, the amount of guidance present in the specification, the absence of data indicating that the symptoms (or disease) of cancer do not occur when a subject is administered a compound of formula I and the state of the prior art indicating that a specific use of formula I is not set forth in the art, treatment, not prevention, using a compound of formula I is possible.

The amount of guidance necessary to perform Applicant's invention would result in undue experimentation because the skilled artisan would be forced to randomly test numerous conditions and amounts of compounds of formula I to determine which combination prevents cancer. Hence, the amount of guidance present in the specification fails to present the necessary instruction such that one can readily determine the appropriate conditions/amounts of the claim.

Note: The Examiner reviewed Applicant's specification, but noted that the data does not indicate prevention of cancer. The data in the specification indicates that tumor cell lines were sensitive to a compound encompassed by formula I.

112 SECOND PARAGRAPH REJECTIONS

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1, 2, 4, and 5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 2: Claim 1 as written does not include a period at the end of the sentence. Thus, it is unclear whether Applicant intended to add more text or not. Since claim 1 is ambiguous, claim 2 which depends on claim 1 is also ambiguous.

Claims 4 and 5: The claims as written are ambiguous because they do not contain a period. Thus, it is unclear if Applicant intended to add more text.

102 REJECTIONS

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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7. Claims 3-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Golub et al, Zh. Obshch. Khim. 1969, 39(6), 1382-1387.

Golub et al disclose two lanthanide chlorides [tris (1,10-phenanthroline)-triselenocyanate lanthanum (3+) and tris (2,2-bipyridine) – triselenocyanate lanthanum (3+)] that are prepared in water (see entire document, especially, abstract) that are encompassed by the instant invention (see Applicant's claims 4 and 5 wherein the specific structures are disclosed) Thus, both Applicant and Golub et al disclose a composition comprising a compound of formula I.

8. Claims 3 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Eremin et al, Zh. Neorg. Khim. 1976, 21(2), 387-394.

Eremin et al disclose two lanthanide chlorides [tris (1,10-phenanthroline)-trithiocyanate lanthanum (3+) and tris (1,10-phenanthroline)-tribromide lanthanum (3+)] that are prepared in water which are encompassed by the claim limitations of the instant invention. In particular, the structure of claim 4 is disclosed by Eremin et al (see entire document, especially, abstract). Thus, both Applicant and Eremin et al disclose a composition comprising a compound of formula I.

COMMENTS/NOTES

9. Applicant is reminded that a recitation of intended use carries no patentable weight in a product claim. Thus, the medicament as set forth in claim 3 is interpreted as

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a product (composition) comprising a compound of formula I and a pharmaceutically acceptable carrier.

10. It should be noted that no prior art has been cited against claims 1 and 2 above; however, Applicant MUST address and overcome the 112 rejections below. In particular, the claims are distinguished over the prior art of record because the prior art neither anticipates nor renders obvious a compound of formula I as set forth in independent claim 1 (the prior art does disclose compounds that have been excluded from the instant invention).

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



D. L. Jones
Primary Examiner
Art Unit 1618

June 24, 2005